UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

MEDICIS PHARMACEUTICAL CORPORATION and ALYZAN, INC.	)	
Plaintiffs,	)	
v.	)	CIVIL ACTION NO. SA-10-CA-621-OG
STIEFEL LABORATORIES, INC.	)	
Defendant.	)	

ORDER DENYING TEMPORARY RESTRAINING ORDER

Pending before the Court is Plaintiffs' Motion for Temporary Restraining Order (Dkt. # 23). Plaintiffs (collectively "Medicis") are seeking injunctive relief against Defendant Stiefel Laboratories, Inc. ("Stiefel") to prevent Stiefel from launching its new competing product, Veltin.™ Stiefel was given notice of the motion, and both parties filed extensive briefs with supporting evidence. The Court held a hearing on the motion, and both sides had an opportunity to present their arguments. After reviewing the motion, response, reply and evidence in support thereof, and after considering the parties' arguments in light of the applicable law, the Court finds that Plaintiffs' motion for temporary restraining order should be denied.

To obtain a temporary restraining order, Plaintiffs must establish each of the following four factors: (1) a reasonable likelihood that they will prevail on the merits; (2) irreparable injury if the injunctive relief is not granted; (3) that their threatened injury outweighs the threatened harm to Defendant; and (4) that granting the injunctive relief will serve the public interest. Altana Pharma AG v. Teva Pharms., USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009); Abbott

Labs v. Andrx Pharms., Inc., 452 F.3d 1331, 1334 (Fed. Cir. 2006). Temporary injunctive relief cannot be granted unless both of the first two factors are firmly established. Amazon.com v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). As always, a temporary restraining order is considered an extraordinary remedy and the movant must clearly carry the burden of persuasion.

A. Reasonable likelihood of success on the merits:

Plaintiffs must show a reasonable likelihood of success on three primary issues raised in the pleadings: (1) infringement of its patent; (2) validity of its patent; and (3) enforceability of its patent. If Defendant raises a substantial question regarding any of these issues, the TRO should be denied. Altana Pharma, 566 F.3d at 1006; Amazon.com, 239 F.3d at 1350-51; Nutrition 21 v. United States, 930 F.2d 867, 869 (Fed. Cir. 1991).

1. Infringement of the '134 patent:

Plaintiffs assert that Stiefel's new product Veltin™ literally infringes Claim 1 of the '134 patent. A patentee can prove a likelihood of infringement by providing evidence that at least one claim in its patent is infringed. In doing so, Plaintiffs must show that each limitation in that claim is likely present in the accused product. Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1344 (Fed. Cir. 2003).

Claim 1 of the '134 patent has a preamble and four limitations. Plaintiffs' expert, Dr. Allen, opines that the formula in Veltin™ meets the preamble and all four limitations in Claim 1. Defendant's expert, Dr. Kibbe, opines that the formula in Veltin™ does not meet the third limitation - thus, there is no infringement.

The third limitation provides "an amount of a high molecular weight polyacrylic acid gelling agent neutralized to a pH of about 3 to 7 effective to form a gel and *hold said retinoid for slow release* in said aqueous medium." (emphasis added). Plaintiffs' expert, Dr. Allen, opines that the Veltin™ formulation contains a carbomer 940 gelling agent that behaves like the Cabopol gelling agent described in the '134 patent and provides a slow release of the active ingredient tretinoin. Defendant's expert, Dr. Kibbe, disagrees and opines that the claim terms "hold said retinoid for slow release" are not met in the Veltin™ formula. According to Dr. Kibbe, the retinoid in Veltin™ is dissolved in the gel and rapidly absorbed into the skin. Thus, while the formula may have certain ingredients embodied in Claim 1 of the '134 patent, Dr. Kibbe asserts that it is a fast acting formula, rather than a slow release formula, and it does not meet the third limitation in Claim 1 of the '134 patent.

While it is difficult at this juncture to draw any conclusions when faced with conflicting expert opinions on claim construction, the Court cannot conclude that Plaintiffs have shown a reasonable likelihood of success on the merits.

2. Validity of the '134 patent:

Defendant contends that Plaintiffs' '134 patent is invalid. To succeed on the merits, the challenger must prove invalidity by clear and convincing evidence. However, the movant in injunction proceedings must carry its burden of showing likelihood of success on this issue as well as others. At this stage, Defendant need only raise a substantial question as to validity. Amazon.com, 239 F.3d at 1358-59; Altana Pharma, 566 F.3d at 1005-06.

Defendant Stiefel contends the '134 patent is invalid because prior art references were never disclosed to the PTO. Through its expert Dr. Kibbe, Defendant states that prior art

abounds in the use of retinoids, and specifically tretinoin, as a topical therapeutic formula. And, the use of polyacrylic acid gels such as Carbopol have been widely known to regulate the release of active ingredients into the skin. Defendant further asserts that the combination of tretinoin formulations and Carbopol were clearly known before the '134 patent. Defendant points to the '108 Felty patent from 1973; the '348 Cioca patent from 1987 (Estee Lauder, patentee); the '353 Bell patent from 1987; the '547 Milstein patent from 1989 (Dow, patentee); the '228 Meybeck patent from 1986; and, the '953 Orr patent from 1987. Defendant claims that these prior art references were relevant and should have been disclosed to the PTO for consideration. Because they were not disclosed, Defendant asserts that the '134 patent is at least vulnerable. See Abbott Labs, 452 F.2d at 1335 ("vulnerability" is the issue at the temporary injunction stage)(citing Amazon.com, 239 F.3d at 1359). Plaintiffs claim that Dr. Kibbe's written declaration is factually incorrect and misleading, but there is no controverting opinion by their own expert at this juncture.

3. Whether the '134 patent is enforceable?

Even if the '134 patent is found to be valid, Defendant contends it is unenforceable based on the doctrines of Equitable Intervening Rights and Equitable Estoppel.

a. Equitable Intervening Rights:

Under this doctrine, Stiefel claims it should not be barred from making and selling a product when substantial preparations were made prior to the issuance of an asserted reissue patent. The asserted '134 patent is a reissue of the '275 patent. In other words, the patentee sought to correct any defects in the original patent. Medicis sent a cease and desist letter to Connetics (Steifel's predecessor) in 2004 about the Velac® formula (predecesssor of Veltin™)

possibly infringing the '275 patent (predecessor to the '134 patent). Connetics responded and explained why it did not believe infringement was occurring. The patentee then initiated reissue proceedings in November 2004, informing the PTO that Connetics' assertions of invalidity caused the applicant to reevaluate the claims in the patent. The patent was not reissued until February 2010 - six years later - and all the claims in the reissued '134 patent were "substantially changed."

In the intervening six years, Stiefel asserts it acted "in good faith" to develop Veltin™ and worked "diligently" with the FDA to approve the product. Defendant states that it has invested substantial resources in research and development, clinical trials, marketing, etc. and should not be shut down on the eve of its launch date simply because Medicis chose to pursue a reissue of the '275 patent rather than enforce it.

Medicis claims that it could not have brought an infringement claim any earlier because Steifel did not provide certification when it filed its new drug application and the FDA did not approve the competing product until July 2010. Velac® was rejected by the FDA in 2005, and when Stiefel acquired the license in 2006 the product went through re-development prior to FDA approval last summer. Thus, Medicis contends it would have been trying to make a claim against a "moving target."

b. Equitable Estoppel:

In the context of patent infringement, there are three elements of equitable estoppel that must be established: (1) the patentee, through misleading conduct, led the alleged infringer to reasonably believe that the patentee did not intend to enforce its patent against the alleged infringer; (2) the alleged infringer relied on that conduct; and (3) due to its reliance, the alleged

infringer would be materially prejudiced if the patentee were permitted to proceed with its infringement action. Aspex Eyewear Inc. v. Clariti Eyewear, Inc., 605 F.3d 1305, 1310 (Fed. Cir. 2010).

Again, Steifel claims that Medicis led both Connetics and Steifel to believe that it would not pursue an infringement action, and Steifel relied on such inaction to its detriment by investing tens of millions of dollars and years of labor in the development of Veltin™. Stiefel has submitted written declarations in support of its claim. In response, Medicis alleges that Defendant has unclean hands and is simply not entitled to equitable relief.

Based on the evidence presented thus far, the Court finds that Defendant has raised a substantial question on validity and/or enforceability.

B. Irreparable Harm:

Medicis also needs to show that it will suffer irreparable injury in the absence of immediate injunctive relief, i.e. that its losses cannot be compensated by an award of damages. Medicis claims that the adverse economic impact will be "substantial and long-lasting" if Veltin™ is released on the commercial market. First, Medicis asserts that an "irreversible" loss of market share will occur immediately and that lost sales could translate into a 35% decrease in net revenue for Ziana®. Medicis also contends Ziana® could lose its status or position on formularies of third party payors, resulting in further lost sales. Given the dynamics of the marketplace, Medicis claims these lost sales would be "difficult to quantify." Medicis also believes that Stiefel will eventually price Veltin™ much lower than Ziana®, resulting in "permanent" price erosion. It claims that price erosion damages are "relatively hard to prove." Medicis further claims that the resulting loss of profits from Ziana® due to the sales of Veltin™

will deprive Medicis of the revenue stream that it relies upon for future research and development of other products. It claims that a reduction in R & D funding is "unpredictable, long-lasting and irreversible" Finally, Medicis asserts that it will need to refocus its promotion efforts on defending Ziana® in the marketplace, and that its promotion of other products will suffer. It believes the loss of promotion cannot be reliably quantified.

Stiefel asserts that any lost sales are calculable and can be compensated by money damages, if necessary. Any loss of market share can be regained in the event Veltin™ is permanently enjoined at the conclusion of the lawsuit. As far as price erosion, Stiefel states that there is no comparison between this situation and a situation in which a generic product floods the market at prices that are discounted up to 80%. Both products in question are patented, and while Stiefel may bring the price down somewhat, the decrease in price that Medicis will need to match will be subject to fairly easy calculation. Stiefel also contends that the status of Ziana® on third party payor formularies will depend in large part on Medicis' own pricing strategy. If they are forced to discount their price to keep their status on formularies, the discount will be calculable. Even if they lose their status, it could be recovered if Veltin™ is later permanently enjoined. Finally, Stiefel cites authority for the proposition that a decrease in R & D is an "amorphous claim" that does not support an injunction. In any event, Steifel claims that Medicis is not completely dependent on its own R & D because it has a history of teaming up with other companies to sell products through licensing agreements, rather than researching and developing all of its own products.

The central inquiry in deciding whether there is a substantial threat of irreparable harm to the plaintiff is whether the plaintiff's injury could be compensated by money damages. Allied

Mktg. Group, Inc. v. CDL Mktg., Inc., 878 F.2d 806, 810 n.1 (5th Cir. 1989); City of Meridian v. Algernon Blair, Inc., 721 F.2d 525, 529 (5th Cir. 1983). An injury is "irreparable" only if it cannot be undone through monetary remedies, i.e., harm for which money damages are inadequate or for which it is virtually impossible to compute money damages. Enterprise Int'l, Inc. v. Corporacion Estatal Petrolera, 762 F.2d 464, 472 (5th Cir. 1985); Deerfield Medical Ctr. v. City of Deerfield Beach, 661 F.2d 328, 338 (5th Cir. 1981). Thus, "[t]he possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weigh[ ]s heavily against a claim of irreparable harm." Enterprise Int'l, Inc., 762 F.2d at 472-73 (quoting Morgan v. Fletcher, 518 F.2d 236, 240 (5th Cir. 1975)).

Again, the Court is faced with conflicting expert declarations and conflicting case law. However, after considering the evidence and hearing the parties' arguments, the Court is persuaded that the potential losses being described herein are calculable and may be compensated by money damages in the event Plaintiffs ultimately prevail.

C. Balance of hardships:

Nor is the Court able to conclude that the threatened injury to Plaintiffs outweighs the potential harm to Defendant. Medicis claims that it stands to suffer a greater hardship due to lost sales, loss of market share, price erosion, disruption of business and loss of good will, and that the hardship will be far reaching.

Stiefel contends that it will suffer the greater harm because it has invested over 40 million dollars and eight years in developing Veltin™, employed a significant research and regulatory team, conducted extensive clinical trials and made considerable preparations for the launch of Veltin™ – including the assembly of a large sales and marketing force that is ready to promote

their product in the market place. Stiefel also expects to have a three year exclusivity deal from the FDA, which prohibits other companies from making a generic version of Veltin™ during this time period. If it is enjoined, that window of opportunity will be greatly diminished, if not lost.

While both sides face potential losses and disruption in their business, the Court cannot conclude that Plaintiffs' threatened injury outweighs the harm to Defendant.

D. Public interest:

Medicis correctly asserts that the public has an interest to uphold patent rights. Stiefel is also correct in asserting that the public has an interest in having access to new medicines at affordable prices. This factor is neutral and does not tip the scale in either party's favor.

It is therefore ORDERED that Plaintiffs' Application for Temporary Restraining Order (Dkt. # 23) is DENIED.[1]

SIGNED and ENTERED on the 20 day of October, 2010.

ORLANDO L. GARCIA
UNITED STATES DISTRICT JUDGE

[1]The decision herein in no way resolves the ultimate questions of infringement, validity and enforceability. Plaintiffs' request for preliminary injunction remains pending and the parties will need to determine how they wish to proceed.